

NOV 15 2004



2042422

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.  
1717 W. Collins Avenue  
Orange, California 92867  
(714) 516-7484 - Phone  
(714) 516-7488 - Facsimile  
Colleen Boswell - Contact Person

Date Summary Prepared: September 2004

Device Name:

- Trade Name – *D3 Chroma*
- Common Name – Orthodontic Bonding Adhesive
- Classification Name – Bracket Adhesive Resin and Tooth Conditioner, per 21 CFR § 872.3750

Devices for Which Substantial Equivalence is Claimed:

- Reliance Orthodontic Products, Inc., *Light Bond*
- 3M Unitek Dental Products Division, *Transbond XT*

Device Description:

*D3 Chroma* is a chromatic orthodontic bonding adhesive. *D3 Chroma* is designed specifically for use with Ormco Damon 3 and Spirit brackets, however bonding of all appliances including metal, ceramic and plastic are indicated. This single paste bonding adhesive has a blue color that enhances ease of use, specifically during bonding and post treatment adhesive remnant removal procedures. During treatment, the patient's body temperature is above the color transition temperature and the adhesive takes on the color of the enamel. *D3 Chroma* has very fast light cure properties and achieves high strength allowing active archwires to be placed immediately. *D3 Chroma* is compatible with traditional etching and sealant procedures, as well as newer self-etching techniques.

Intended Use of the Device:

The intended use of *D3 Chroma* is as a light-cured orthodontic bonding adhesive designed to be used for the attachment of orthodontic appliances to teeth.

Substantial Equivalence:

*D3 Chroma* is substantially equivalent to other legally marketed devices in the United States. *D3 Chroma* functions in a manner similar to and is intended for the same use as the products *Light Bond* and *Transbond XT* cleared for marketing for Reliance Orthodontic Products, Inc. and 3M Unitek Dental Products Division, respectively.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 15 2004

Ms. Colleen Boswell  
Director, Corporate Compliance  
Sybron Dental Specialties, Incorporated  
1717 West Collins Avenue  
Orange, California 92867

Re: K042422

Trade/Device Name: D3 Chroma  
Regulation Number: 21 CFR 872.3750  
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner  
Regulatory Class: II  
Product Codes: DYH  
Dated: September 02, 2004  
Received: September 07, 2004

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K042422

Device Name: *D3 Chroma*

### Indications For Use:

*D3 Chroma* is a light-cured orthodontic bonding adhesive and is intended to be used for the attachment of orthodontic appliances to teeth.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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